

Notice of Allowability

Application No.

10/092,454

Examiner

Anne Marie S. Wehbe

Applicant(s)

PODSAKOFF ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 10/19/06.
2. ☒ The allowed claim(s) is/are 1, 3-4, 7-12, 16, 18, and 20.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

ATTACHMENT TO NOTICE OF ALLOWANCE

Applicant's amendment received on 10/19/06 has been entered. Claims 2, 5-6, 13-15, 17, 19, and 21-22 are canceled. Claims 1, 3-4, 7-12, 16, 18, and 20 are currently pending in the instant application.

Applicant's terminal disclaimer filed on 10/19/06, disclaiming the terminal portion of any patent granted on this application that would extend beyond the expiration date of U.S. Patent No. 6,610,290, is proper and has been entered.

Double Patenting

The rejection of claims 1, 3-4, 7-8, and 10-11 for obviousness-type double patenting over the claims of U.S. Patent No. 6,610,290 is withdrawn in view of the terminal disclaimer filed by the applicant. It is noted that the applicant previously disclaimed the terminal portion of co-owned U.S. Patents 5,858,351, 6,325,998, 5,846,528, and 6,335,011, see the terminal disclaimer filed on 12/22/03.

The rejections of claims 1, 3-4, 7-8, And 10-11 for obviousness-type double patenting over the claims of U.S. Patent No. 6,391,858 (the '858 patent) and U.S. Patent No. 6,211,163 (the '163 patent) are withdrawn in view of applicant's amendment to claim 1 which now recites that the recombinant AAV virion is introduced directly into the muscle cell or tissue. The claims of the '163 patent recite intravenous administration not direct administration to muscle and thus

do not render the instant claims obvious. Further, the claims of the '858 patent recite delivering to the bloodstream or administering into the bloodstream. Neither step in the '858 claims encompasses direct administration to muscle cells. Thus, the newly amended claims are not rendered obvious by the claims of the '858 patent.

Claims 1, 3-4, 7-12, 16, 18, and 20 are considered free of the prior art and allowed.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Roberta Robbins on 12/5/06.

The application has been amended as follows:

1. On page 1 of the specification, line 2, the phrase -- (now U.S. Patent No. 6,391,858) -- has been inserted after "January 4, 2001".
2. On page 33 of the specification, line 24, the phrase -- (SEQ ID NO:1) -- has been inserted before the word "was"; and on line 27, the phrase -- (SEQ ID NO: 2)-- has been inserted before the word "was".

3. On page 34 of the specification, line 11, the phrase “ SEQ ID No.:__” has been replaced by -- SEQ ID NO: 3 -- ; and on line 21, the “ SEQ ID NO.:__” has been replaced by --SEQ ID NO: 4 --; and on line 22, “ SEQ ID NO.:__” has been replaced by --SEQ ID NO: 5 --.

4. On page 35 of the specification, line 5, the phrase -- (SEQ ID NO:2) -- has been inserted before the word “were”.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner’s supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner’s direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO’s Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for

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electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', with a long horizontal stroke extending to the right.